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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,001	05/23/2006	Dhiraj Sardar	UTSJ:041US/10507807	1190

32425 7590 06/16/2011

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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
06/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/543,001	SARDAR ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-35,37,39 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 23-35, 37, 39 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1-5, 9-13, 17-18, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Van de Velde (US Pat: 5,568,208) and further in view of Freeman (Pub. No.: US 2006/0258629) and Pang (US Pat: 6,179,421).

Regarding claims 1, 3-4, 11-12, 29, 31-33 and 25-27, Dreher et al disclose system and method to diagnose diseases of the eye that anticipates the claimed invention. Dreher et al FIGS. Ia and 1 illustrates the eye 11, in which the cornea 10 serves as the foremost, transparent portion of the eye, behind which is the iris 12 and the lens 14. The interior of the eye 11 is of course filled with vitreous and at the rear of the eye is what is generally termed the retina composed of the layers illustrated, in FIG. 1, including the internal limiting membrane 16, the nerve fiber layer 18, the receptor system 20, the retinal pigment epithelium 22, and the choroid 23 [see column 3 lines 47-54]. Fig 1 shows light beams go through the retina and backscattered and fig 7 also shows light beams 50 go through the entire eye 11 and backscattered to the direction where they came from (emphasis added).

Dreher et al disclose a polarization technique that has the ability to diagnose the interior eye, especially early diagnosis of glaucoma [see column 8 lines 60-63]; a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5] and fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). As disclosed

herein, the detector detects absolute intensity which means maximum intensity and thereby can detect the maximum of either one of the beams (emphasis added). Dreher et al further teach a variable retarder to adjust to maximize the intensity of the light in the polarized state [see column 5 lines 50-53].

Dreher et al teach a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33- 40]. Dreher et al also teaches an ellipsometer to capture and analyze polarization information [see column 6 lines 6-9]; incident diagnostic beam could be scanned by a scanning unit [see column 6 lines 65- 68]; choroid (or choroidal tissue) [see column 3 lines 55-56].

Dreher et al don't explicitly mention neovascularized tissue.

Nonetheless, Freeman discloses the use of external diagnostic light sources [see 0068], imaging light beam comprises polarized light [see 0069-0070] for diagnosing an "ocular neovascular disease". Freeman discloses an "ocular neovascular disease" is a disease characterized by ocular neovascularization, i.e. the development of abnormal blood vessels in the eye such as retinopathy; intraocular, retinal, choroidal and corneal neovascularization, macular degeneration, , diabetic macular edema, diabetic and proliferative diabetic retinopathy [see 0027].

In addition, Pang discloses a method to diagnose neovascularized tissue by using a light source to direct light into the region of interest [see column 2 lines 40-50, column 3 lines 43-45].

Furthermore, Van de Velde teaches backscattered light form the eye [see fig 1 beam 18 and column 4 lines 18-20].

Therefore, one skilled in the art at the time the invention was made would have been motivated to combine Dreher et al with Pang, Van de Velde and Freeman by using light beam backscattered off of neovascularized tissues; because they are highly disorganized and exhibit functional abnormalities; thereby facilitating the diagnosis and to provide the best possible treatment since age-related macular degeneration (AMD) with choroidal neovascularization (CNV) commonly leads to rapidly progressive loss of sight [see 0023, Freeman].

Regarding claims 5, 34, 28 and 13, Dreher et al teach the system uses a laser diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44, and column 6 lines 30-50].

Regarding claims 2, 30, 24, 18 and 10, all other limitations are taught as set forth by the above teaching. Dreher et al teach a non invasive diagnosis [see fig 3].

Regarding claim 9, Dreher et al further teach a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5] so fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). As disclosed herein, the detector detects absolute intensity which means maximum intensity and thereby can detect the maximum of either one of the beams (emphasis added).

Regarding claims 17 and 23, Dreher et al teach a detector that measures absolute intensity of returned diagnostic beams [see column 7 lines 65-67, column 8 lines 1-5] and fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). Dreher et al teach a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33- 40]. The invention measures polarization shift of the most intense light beam since Dreher et al disclose the detector detects absolute intensity (which is the most intense, emphasis added) of returned beams; therefore, the polarization sensitive detection means has to measure shits of the most intense beam (s) (emphasis added). Dreher et al teach a second photo detector is used to measure the total amount of reflected intensity of the return diagnostic beam at the corresponding points on the fundus. By normalizing the intensity values obtained with the first photo detector with the corresponding values of the second detector, absolute changes in the state of polarization of the return diagnostic beam are calculated [see column 8 lines 43-50 and column 8 lines 20-31] and means and method for determining thickness of the nerve fiber layer of the fundus of the eye by measuring the polarization shift of the reflected probing light.

2. Claims 6-8 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Van de Velde (US Pat: 5,568,208) and further in view of Freeman (Pub. No.: US 2006/0258629) and Pang (US Pat:

6,179,421) as applied to claim 1 above and further in view of Glaser et al (US Pat: 5,767,079) or Larrick et al (US Pat: 5,670,151).

Regarding claims 6-8 and 14-16, Dreher et al don't mention diabetes retinopathy, macular degeneration and cancer.

However, However, Glaser et al teaches method for treating ophthalmic disorders like retinal disorders, choroidal tissue, macular degeneration, neovascularization, diabetic retinopathy, ocular tumor [see column 5 lines 39-43, lines 62-67, column 1 lines 33-36 and column 6 lines 1- 13].

Larrick et al teaches a form of disorder of the eye is diabetes retinopathy [see column 2 lines 13-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combined Dreher with Glaser et al or Larrick et al; for the purpose of providing diagnosis to evaluate the extent or spread of the disease as to prescribe the best possible treatment; thus prevent any further eye problems or blindness.

3. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Van de Velde (US Pat: 5,568,208) and further in view of Freeman (Pub. No.: US 2006/0258629) and Pang (US Pat: 6,179,421) as applied to claim 1 above and further in view of Hay et al (US Pat: 5,632,282).

Regarding claim 19, Dreher et al further teach an array of polarizers, a micro computer, a diagnostic beam, beam splitter, ADC [see fig 3]; the system uses a laser

diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44]; a linear polarizer, a laser, laser diagnostic beam, array of polarizers, computer that is coupled to the detectors and the analyzer [see column 6 lines 30-50].

Dreher et al don't mention a sample tissue holder.

Nonetheless, Hay et al teach a device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24] and stabilizing bar to stabilize the head and thus the eye [see column 8 lines 22-24].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Dreher et al with Hay et al by using a sample holder as taught by Hay et al; in order to stabilize the desired examined area thereby to precisely and accurately focus the laser beam into the eye.

4. Claims 20-21 and 35, 37, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Van de Velde (US Pat: 5,568,208) and further in view of Freeman (Pub. No.: US 2006/0258629) and Pang (US Pat: 6,179,421) as applied to claim 1 above and further in view of Hay et al (US Pat: 5,632,282) as applied to claim 19 above and further in view of Trachtman (US Pat: 5,002,384).

Regarding claims 20, 35, 39 and 42, Dreher et al don't mention photodiode detector and tissue sample holder.

However, Hay et al teach a device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24].

However, Trachtman teaches an apparatus for monitoring and training eye position under clinical conditions, sensors means can be photodiodes [see column 16 lines 41-56]; sample holder [see column 19 lines 8-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Dreher et al with Trachtman by using its photodiode; for the purpose of having the capability of converting light into either current or voltage, depending upon the mode of operation; and with Hay et al by using its tissue holder; in order to stabilize the desired examined area thereby to precisely and accurately focus the laser beam into the eye.

Regarding claims 21 and 37, Dreher et al don't teach digital meter.

Nonetheless, Trachtman teaches a digital meter [see column 19 lines 25-35 and 45-55].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Dreher et al with Trachman by using the digital meter for higher accuracy, efficacy and greater precision.

Response to Arguments

5. Applicant's arguments with respect to claims 1-21, 23-35, 37, 39, 42 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Dreher et al don't teach backscattered beam.

The examiner disagrees because backscattering is defined as the reflection of waves or signals back to the direction they came form and it is a diffuse reflection due to scattering (emphasis added). So Dreher et al teach light reflected from the eye is similar to backscattered light (emphasis added).

Applicant argues that Dreher et al eliminate reflected light. The examiner disagrees because Dreher et al do teach the teaching of light backscattered from eye tissue because Fig 1 shows light beams go through the retina and backscattered and fig 7 also shows light beams 50 go through the entire eye 11 and backscattered to the direction where they came from (emphasis added).

Applicant also mentions that the light go through the entirety of the eye tissue. That limitation is not part of any claim and both figs 1 and 7 show that light beams go through the entire eye [see figs 1 and 7].

Applicant mentions that Dreher et al invention is to measure nerve thickness and not to diagnose diseases.

Examiner disagrees because Dreher et al teach their invention concerns itself primarily with the cornea, the lens, and the nerve fiber layer 18. It is this nerve fiber layer's topographical and the thickness measurements which are crucial to the diagnosis of certain diseases, principal among which is glaucoma [see column 3 lines 54-60].

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Thu 9:30 AM to 7:00 PM (Off Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777